

Attorney Docket No. 6714/46501  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth Stewart Confirmation No. 6917  
Serial No.: 10/634,368 Art Unit: 3735  
Filed: August 6, 2003 Examiner: Nelson, Christine L  
For: Bone Instrumentation Cover Or Shield

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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**23646**

U.S. Patent and Trademark Office

Sir:

I, Jeffery Thramann believe and declare as follows:

I am a founder and currently serve as Chairman of the board of Lanx, Inc. Lanx, Inc. manufactures and supplies spinal instrumentation to purchasers in the United States and abroad. I received a medical degree from Cornell University and completed general surgical training as well as neurosurgical training and a spine fellowship at the Barrow Neurological Institute. I have performed thousands of surgeries on and about the human spine including the placement of implanted spinal instrumentation. Such spinal instrumentation includes screws, hooks, rods, plates, and interbody cages and grafts. I also am acquainted with surgical treatment throughout the human body from my studies and associations with other surgeons.

I am aware of the statement in the 08 February 2010 office action in the above-identified application that "Barron discloses a bone instrumentation protective cover, or barrier material, for isolating bone implants that are installed in the body." However, it is my opinion that Barron discloses exactly the opposite of the statement in the office action.

Barron discloses "bioresorbable, bone anchor protective covers . . . for isolating bone anchors to reduce accidents with the sharp bone anchor tip and/or edges **before** it is inserted into a target site" (emphasis added) [Abstract and 0009].

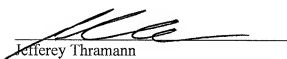
Barron explains the dangers of bone anchors for attaching sutures, tissue, and/or bone to bone in various surgical procedures known in the art [para 0002]. For example, such an anchor may be inserted into a bone and used to connect a suture to the bone that is then used to tie another tissue down to the bone where the anchor is inserted into the bone. Other examples include attaching hearing aids and treating bunions. [0003 - 0004] Barron states clearly that “[s]urgical insertion of a bone anchor entails placing a small sharp object into a patient’s bone, often in hard-to-reach sites. Such procedures are susceptible to accidental sticks or drops resulting in injuries to the patient and/or the surgeon.” [0006] Because of this danger, Barron proposes a device “to reduce accidents, for example, puncture of a doctor’s glove, abrasion of the patient’s tissue or insertion of the bone anchor tip into tissue other than the target tissue.” [0010] Barron’s cover encapsulate’s the bone anchor prior to insertion, isolates it during insertion toward the implantation site on the bone, and is then penetrated by the bone anchor to expose the bone anchor tip so that the bone anchor can engage the surrounding tissue. [0009, 0017, 0030, 0031].

Barron further discloses that it is undesirable for a non-resorbable cover to “remain, in part or in whole, in the body”. [0006] Rather, Barron discloses that the cover should be made of a material that “erodes or is dissolved within the patient after a period of time. Thus, following implantation of the bone anchor, the protective cover material is absorbed by natural biological processes.” [0012] “The bioabsorbable material dissolves within 90 days. . . . [Preferably] within 30 days.” [0032] These statements by Barron emphasize that his cover is a pre-placement protective cover that is not needed after implantation and therefore does not persist.

In summary, Barron discloses a cover that does not isolate bone implants that are installed in the body.

- Barron’s cover is applied to the anchor before use to protect the patient and surgeon during introduction of the device toward the surgical site.
- Barron’s cover covers the portion of the anchor that is to be inserted into bone
- Barron’s cover must be punctured in use to expose the anchor to surrounding tissue to permit the anchor to be inserted into bone
- Barron’s cover is made of a resorbable material that goes away and thus is incapable of providing long term isolation of any portion of the anchor from surrounding tissues.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.



Jefferey Thramann

5/17/10  
Date